REMARKS

In the Office Action dated January 4, 2007, claim 22 was examined with the result that claim 22 was rejected. The rejection made by the Examiner is non-final. In response, applicant has filed this Amendment, and in view of the following comments respectfully requests reconsideration of the present claims.

In the Office Action, claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLuca et al U.S. 6,114,317. The Examiner states that the '317 patent teaches a method of modifying or altering the structure of vitamin D compounds to increase its biological activity. The Examiner indicates that the presently claimed compound in claim 22 is broadly encompassed by the genus of the formula set forth at the top of column 5 of the '317 patent. In addition, the Examiner states that the '317 patent exemplifies an embodiment illustrated at the top of column 12 of the '317 patent that is closely related to the currently claimed compound of claim 22. Accordingly, the Examiner believes it would be obvious to one with ordinary skill in the art to select the currently claimed compound since one of ordinary skill would expect it to possess increased biological activity. Applicant, however, respectfully disagrees for the following reasons.

First, applicant directs the Examiner to the biological data found in Figure 1 of the present patent application as well as the description thereof found at page 17, lines 8-9. As the Examiner can see, the presently claimed compound of claim 22 has binding activity to the VDR that is less than 1α,25-dihydroxyvitamin D_3. In fact, as illustrated in Figure 1, the presently claimed compound of claim 22 has at least one order of magnitude less binding activity than 1α,25-dihydroxyvitamin D_3. This is illustrated, for example, at the value for 8,000 DPM's bound wherein a concentration of approximately 1.0×10^{-9} is required of 1α,25-dihydroxyvitamin D_3 to obtain such binding activity. However, with respect to the 2-methylene analog claimed in claim 22, it requires about 1.0×10^{-8}

concentration to obtain the same level of DPM's bound. Thus, the presently claimed compound of claim 22 is significantly less active than 1α,25-dihydroxyvitamin D_3 in binding to the VDR.

The point of the above comparison is that the presently claimed compound of claim 22 does not have increased biological activity as compared to 1α,25-dihydroxyvitamin D_3 (the natural hormone and the standard vitamin D compound against which other vitamin D compounds are typically compared) as it relates to binding to the VDR. If the Examiner's conclusion based on the teaching of the '317 patent is that it would be obvious to one of ordinary skill in the art that the claimed compound would possess increased biological activity, then why does the compound in fact have decreased biological activity with regard to binding activity to the VDR? Under the Examiner's theory, one would expect the compound of claim 22 to have increased biological activity, especially binding activity to the VDR, but just the opposite is true, i.e. it has less binding activity than 1α,25-dihydroxyvitamin D_3.

To further support applicant's position, applicant refers the Examiner to DeLuca et al U.S. 5,843,928 which was cited in the Information Disclosure Statement dated October 21, 2003. Applicant refers the Examiner to the data found in Figure 1 of the '928 patent. The data in Figure 1 is a comparison of the binding activity to the VDR of 20S-2-methylene-19-nor-1α,25-dihydroxyvitamin D_3 as compared to 1α,25-dihydroxyvitamin D_3. Applicant believes the compound 20S-2-methylene-19-nor-1α,25-dihydroxyvitamin D_3 (referred to in the '928 patent as 2MD) is the closest prior art compound to that claimed in the present claim 22. The only significant difference between the compound in present claim 22 and the vitamin D compound 2MD is that 2MD has a 25-hydroxyl group and the presently claimed compound of claim 22 does not have a hydroxyl group at the 25 carbon position.

A comparison of the binding data of 2MD to 1α,25-dihydroxyvitamin D_3 shows that 2MD binds substantially the same, or equally as well, to the VDR as 1α,25-dihydroxyvitamin D_3. This is supported by the statement at column 15, lines 57-59 of the '928 patent. In contrast, a review of the binding data of the compound of present claim 22, as described above, shows that it has one order of magnitude less binding activity than 1α,25-dihydroxyvitamin D_3. Thus, based on structural similarity, one would expect the compound of claim 22 to have the same or very similar binding activity as the compound 2MD. Also, based on the teachings in the '317 patent, one skilled in the art would expect the presently claimed compound of claim 22 to have increased biological activity. However, in fact, the compound of present claim 22 has less binding activity to the VDR than either 2MD or 1α,25-dihydroxyvitamin D_3. Thus, applicant believes the compound of claim 22 would not be obvious to one skilled in the art in view of what is disclosed in the '317 patent and/or the '928 patent.

Applicant respectfully requests the Examiner withdraw the § 103(a) rejection of claim 22.

An effort has been made to place this application in a condition for allowance and such action is earnestly requested.

Respectfully submitted,

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